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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/895,686	06/28/2001	Olga Bandman	PC-0044 CIP	7340

27904 7590 10/17/2002

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EXAMINER
O HARA, EILEEN B

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 10/17/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/895,686	BANDMAN ET AL.	
	Examin r	Art Unit	
	Eileen B. O'Hara	1646	

-- The MAILING DATE of this c mmunication appears on the c ver sheet with the correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *7-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-12* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-12 are pending in the instant application. Claims 1, 2, 7 and 10 have been amended and claims 13-20 have been canceled as requested by Applicant in Paper Number 8, filed August 9, 2002.

Election/Restrictions

2. Applicant's election with traverse of Group A, claims 1-6, and Group I within Group A, in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the inventions of Groups B and C are methods of use within the scope of the elected invention and should be examined at the same time. This is not found persuasive because consistent with current patent practice, a serious search burden may be established by (A) separate classification thereof: (B) a separate status in the art when they are classifiable together: (C) a different field of search:. These criteria were met in the above restriction. As stated in the MPEP § 803, "a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02.". It is noted that Applicants will ask for rejoinder of Groups B and C, claims 7-12, at the time that the product claims are allowed under In re Ochiai, In re Brouwer, and 35 USC § 103(b).

The requirement is still deemed proper and is therefore made FINAL.

Claims 7-12 are withdrawn as being drawn to a non-elected invention.

Claims 1-6 are currently under examination.

Priority

3. This application filed under former 37 CFR 1.60 lacks the current status of the nonprovisional parent application 09/516,513. A statement reading "(now abandoned)" should be included after "09/156,513, filed 17 September 1998" following the title of the invention.

Specification

4. The disclosure is objected to because of the following informalities: On page 10, line 26, the specification states that transcript imaging is shown in Example VIII, however, the transcript imaging is shown in Example VII on pages 34-37.

Appropriate correction is required.

Claim Rejections - 35 USC § 101 and § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 1-6 are directed to isolated cDNA's encoding the amino acid sequence of SEQ ID NO: 1 or the complement of the encoding nucleic acid sequence, or cDNA comprising the nucleotide sequence of SEQ ID NO: 7. The instant specification discloses that the polypeptide comprising the amino acid sequence presented in SEQ ID NO:1 is presumably a member of the G-protein coupled receptor (GPCR) superfamily identified as a metabotropic GPCR, based on

homology to that family of proteins (Fig. 1). However the protein and encoding nucleic acids do not have any specific and substantial utility, or a well established utility, as determined according to the current Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday, January 5, 2001.

The specification describes the uses and methods of the invention, in which the proteins and nucleic acids can be used in methods such as screening assays to identify ligands and binding compounds, methods to inhibit or regulate expression of the nucleic acid or polypeptide, use of the nucleic acids as probes to identify orthologs or related genes from the same species or to screen cDNA libraries or genomic libraries, to make transgenic or knock out animals to produce mammalian model systems, to raise monoclonal or polyclonal antibodies, to detect the differential expression of a nucleic acid in a sample, to make a microarray, or to identify chromosomes or location of particular sites on a chromosome, or to express the nucleic acid in order to make the protein.

However, none of these uses are considered to be specific or substantial utilities for either the protein or the encoding nucleic acid molecules. Methods such as identification of ligands, use to screen for homologous genes, use to identify chromosomes or chromosomal location, use to recombinantly produce protein or use to generate antibodies are considered general methods applicable to any protein and/or nucleic acid, and are not considered specific or substantial.

The instant application also teaches that the nucleic acids, proteins and associated antibodies and antisense nucleic acids can be used to can be used either diagnostically to detect abnormal levels of the protein or nucleic acids and associated disorders or diseases, or

therapeutically to treat diseases or disorders, such as infection, inflammation and cancer, and particularly meningioma of the brain. However, the assertion that the protein and/or nucleic acids of the instant invention can be used in the diagnosis or treatment of diseases or disorders is also not a specific and substantial utility, and is based on the fact that the cDNA encoding the human receptor of SEQ ID NO: 1 was first identified from a brain meningioma cDNA library.

Applicant's provide information from transcript images on pages 34-35, in which cDNA libraries from different tissues were assayed for abundance of the nucleic acid of SEQ ID NO: 7. The first library, from thyroid tumor, follicular CA, CGAP, had an abundance of 1 and % abundance of 0.0344, the second library, from thyroid, mw/follicular adenoma, 28F, had an abundance of 4 and % abundance of 0.0250, and the third library, thyroid, mw/papillary CA, 56M, had an abundance of 1 and % abundance of 0.0075. From this information, Applicant's state that SEQ ID NO: 7 was differentially expressed in follicular carcinoma of the thyroid and expression was 4-fold higher than in any other thyroid tissue. It is not clear from the information in the specification how the numbers in the abundance and % abundance were derived, or what these numbers mean, so it is difficult to interpret their meanings. Applicant's also state that the sequence was not expressed in cytologically normal thyroid (5 libraries), lymphocytic thyroiditis (2 libraries), hyperthyroidism, goiter or papillary carcinoma. From this it is interpreted that the abundance in these libraries would be 1, as in the first library, from thyroid tumor, follicular CA, CGAP, and the third library, thyroid, mw/papillary CA, 56M. However, although applicants state that SEQ ID NO: 7 is diagnostic of thyroid tumor and specifically follicular carcinoma, the increase in abundance was not seen with the first and third libraries in the comparison, which are from cancerous tumors. Also, the assertion that the nucleic acid molecule can be used

diagnostically is based on the result from a single library. The skilled artisan would not find it credible that this nucleic acid could be used diagnostically to detect follicular carcinoma of the thyroid based on a slight increase in expression of the gene from a single library from one tissue source. Even if the data demonstrated a slight increase in expression in such a tumor, such would not be indicative of a use of the nucleic acid as a diagnostic agent. Cancerous tissue is known to be aneuploid, that is, having an abnormal number of chromosomes (see Sen, 2000, Curr. Opin. Oncol. 12:82-88). The data presented in the specification were not corrected for aneuploidy. A slight amplification of a gene does not necessarily mean overexpression in a cancer tissue, but can merely be an indication that the cancer is aneuploid. Further, overexpression of a given sequence in a single isolate would not be considered by a person of ordinary skill in the art to be predictive of diagnostic utility for that type of tumor. Thus, the data do not support the implicit assertion that the nucleic acid can be used as a cancer diagnostic. Significant further research would have been required of the skilled artisan to determine whether the nucleic acid molecule of SEQ ID NO: 7 is overexpressed in any cancer to the extent that it could be used as a cancer diagnostic, and thus the asserted utility is not substantial.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-6 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1 and 3-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 3-6 are indefinite because claim 1 encompasses a cDNA encoding a nucleic acid encoding a protein and the complement thereof, but a cDNA is double stranded and therefore already includes the complement of the encoding strand.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

35 U.S.C. § 120 states that:

> An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

8. Claims 1 and 3-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Valenzuela et al., WO 99/55721, Nov. 4, 1999. Applicant is advised that the instant application can only receive benefit under 35 U.S.C. § 120 from an earlier application which meets the requirements

of 35 U.S.C. § 112, first paragraph, which respect to the now claimed invention. Because the instant application does not meet the requirements of 35 U.S.C. § 112, first paragraph, for those reasons give above and it is a continuation of application Serial Number 09/516,513, the prior application does not meet those requirements and, therefore, is unavailable under 35 U.S.C. § 120. The effective priority date of the instant application is considered to be the filing date of this application, June 28, 2001, because the claimed invention is not supported by either a specific and substantial utility or a well established utility.

Claims 1 and 3-6 encompass an isolated cDNA comprising a nucleic acid sequence encoding the polypeptide of SEQ ID NO: 1, vector and host cell comprising the cDNA, method of using the cDNA to produce the encoded protein, and composition comprising the cDNA and a labeling moiety.

Valenzuela et al. disclose a nucleic acid molecule (SEQ ID NO: 43, claim 52) that encodes a protein (SEQ ID NO: 45, claim 53) that is 100% identical to the polypeptide of SEQ ID NO: 7 of the instant application. Valenzuela et al. also teach vectors (Figures 1A and 1B), host cells (pages 137 and 146), method of producing protein (pages 246-147) and labeled DNA (page 149). Therefore, Valenzuela et al. anticipates the claims.

Conclusion

9.1 No claim is allowed.

9.2 Claim 2, directed to an isolated cDNA comprising the nucleic acid sequence of SEQ ID NO: 7, is free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

LORRAINE SPECTOR
PRIMARY EXAMINER